REMARKS:

In response to the Office Action mailed December 19, 2008, claims 1, 23, and 29 have been amended. Therefore, claims 1-15 and 23-34 remain pending. Support for the amendments may be found throughout the original disclosure, for example, in the specification, e.g., in paragraphs [0019], [0033]-[0035], [0043], and [0044], and in the drawings, e.g., in FIGS. 3, 4, 6B, and 6C. No new matter has been introduced.

In the Office Action, claims 1, 23, and 24 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,682,556 ("the Ischinger reference"), claims 1, 7, 9-11, 15, 23-25, 27, and 28 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,458,151 ("the Saltiel reference"), and claims 23, 26, 29, 33, and 34 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Publication No. 2004/ 0111143 ("the Fischell reference"). In addition, claims 2-6 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Saltiel reference in view of U.S. Patent No. 6,589,214 ("the McGuckin et al. reference"), claims 1, 8, 12-14, 29, 30, and 31 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Fischell reference in view of U.S. Patent No. 6,572,612 ("the Stewart et al. reference"), and claim 32 was rejected under 35 U.S.C. § 103(a) as unpatentable over the Shaknovich reference in view of the Fischell reference in view of U.S. Patent No. 5,702,418 ("the Ravenscroft reference").

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the § 102(b) rejections, as explained in Applicant's previous response, the Ischinger reference discloses a balloon catheter that includes a first guidewire channel 16 that extends to the distal end 10 of the catheter beyond the balloon, and a second guidewire channel

14 with a distal exit 11 located adjacent the balloon. Col. 2, lines 56-63, col. 3, lines 10-13; FIGS. 1A, 2A. During use, a first guidewire 12 is placed in the target sidebranch artery and a second guidewire 15 is placed in the main artery. Col. 3, lines 59-63. The first guidewire 12 is threaded into the first channel 16, the second guidewire 15 is threaded into the second channel 14, and the catheter is advanced over the guidewires 12, 15 until the distal exit 11 of the second channel 14 reaches the bifurcation and prohibits further advancement. Col. 3, line 64 through col. 4, line 5. Alternatively, the second guidewire 14 may be preloaded in the second channel 14 and advanced through the distal end 11 once the catheter is inside the patient. Col. 4, lines 5-12. The feature 100 shown in FIGS. 2A, 4A, and 4B is merely described in the Ischinger reference as a pig-tail shape tip that optionally may be provided on the second guidewire 15. Col. 4, lines 29-34. The balloon catheter may be used to deliver a stent 40, 90 mounted on the balloon beyond the distal exit 11.

Turning to the present claims, claim 1 recites an apparatus for locating an interventional device relative to the ostium of a branch vessel that includes a sheath having proximal and distal ends, and a lumen extending therebetween, the sheath adapted to be affixed to an interventional device; and an ostial locator wire slidably disposed within the sheath, the ostial locator wire having a distal region initially provided in a retracted configuration within the lumen and that assumes an expanded configuration when extended from the distal end of the sheath such that the distal region helically encircles and is spaced apart from an interventional device when the sheath is affixed thereto and that assumes the retracted configuration when retracted back into the lumen, the sheath being advanceable with the distal region in the expanded configuration to position the interventional device relative to the ostium, the ostial locator wire and sheath being removable

after positioning the interventional device.

The Ischinger reference does not disclose, teach, or suggest an ostial locator wire having a distal region initially provided in a retracted configuration within a lumen of a sheath and that assumes an expanded configuration when extended from the sheath such that the distal region ***helically encircles*** and is spaced apart from an interventional device when the sheath is affixed thereto and that assumes the retracted configuration when retracted back into the lumen. The pig tail tip 100 of the guidewire 15 is ***structurally incapable of helically encircling*** anything. More particularly, neither the guidewire 15 nor the pig tail tip 100 helically encircles the stent 40, 90 disclosed in the Ischinger reference. As clearly shown in FIG. 2A, at most, the guidewire 15 extends axially parallel to the stent 40, and the pig tail 100 extends away from the stent 40 and coils on itself. The coils of the pig tail 100 are clearly too small and incapable of helically encircling the stent 40, as can be seen in FIG. 2A. For these reason, claim 1 and its dependent claims are neither anticipated by nor otherwise obvious over the Ischinger reference.

For similar reasons, claim 23 and its dependent claims are also neither anticipated by nor otherwise obvious over the Ischinger reference. Similar to claim 1, claim 23 recites an ostial locator that assumes an expanded configuration when extended from the distal end of a sheath and ***helically encircles*** and is spaced apart from a stent. Such a locator is not taught or suggested by the Ischinger reference and the disclosed pig tail 100 is incapable of meeting the claimed structure, as explained above.

Turning to the Saltiel reference, a stent positioning device 10 is disclosed that includes an elongate shaft 12, a manifold 14 on the proximal end, and an expandable member 20 on the distal end of the shaft 12. Col. 3, lines 5-12. A sheath 30 is slidably disposed about the stent

positioning device 10 between an advanced position and a retracted position. Col. 4, lines 4-8. In the advanced position, the sheath 30 covers and constrains the expandable member 20 to facilitate insertion of the stent positioning device 10. Col. 4, lines 8-13. The sheath 30 may be retracted to gradually allow expansion of the expandable member 20. Col. 4, lines 12-15.

As disclosed in the Saltiel reference, the expandable member 20 is a tubular braid or mesh that is radially resilient but ***longitudinally rigid*** body 22 such that an overall length of the stent positioning device 10 does not change when the distal end 24 of the expandable member 20 engages the ostium of a vessel. Col. 3, lines 32-50.

First, with respect to claims 1, 23, and 29, the Saltiel reference fails to disclose, teach, or suggest an ostial ***locator wire*** or an ostial locator including a distal region that assumes an expanded configuration when extended from a sheath such that the distal region ***helically encircles*** and is spaced apart from an interventional device. In addition, the Saltiel reference does not disclose, teach, or suggest an ostial locator comprising a distal region that assumes a ***spiral shape*** in the expanded configuration ***that is flattened out axially*** when the sheath is advanced into an ostium, as recited in claim 29 (and claims 13 and 26). In direct contrast, the Saltiel reference discloses an expandable member that is ***longitudinally rigid*** such that an overall length of the stent positioning device 10 does not change. Thus, the Saltiel device merely stops abruptly when it contacts an ostium, while the claimed ostial locator flattens out axially as it contacts an ostium, thereby providing tactile feedback regarding the position of the distal region, e.g., due to the increased resistance of the ostial locator as it flattens.

Accordingly, for these reasons, claims 1, 23, and 29 and their dependent claims are neither anticipated by nor obvious over the Saltiel reference.

Turning to the Fischell reference, an ostial positioning introducer sheath 20 is disclosed that includes an expandable distal end flange 23 and a guiding catheter 40. ¶ [0014]. The flange 23 is in the form of a flower-like arrangement with multiple petals. ¶ [0018]. Initially, the sheath 20 is provided with the expandable flange 23 in an unexpanded state within the guiding catheter 40, e.g., such that the guiding catheter 40 can be advanced until its distal end is within an ostium of an artery. ¶¶ [0017], [0020]. The sheath 20 is then advanced through the guiding catheter 40 until the expandable flange 23 extends out and expands, and then the guiding catheter 40 is pushed forward to position the flange 23 against the ostium, as shown in FIG. 6. ¶¶ [0018], [0020]. A stent 18 may then be delivered within the vessel on a stent delivery device 12 advanced through the guiding catheter 40, sheath 20, and flange 23. ¶ [0021], FIG. 6.

First, the Fischell reference fails to teach or suggest anything about an ostial locator having a distal region that assumes an expanded configuration when extended from the distal end of a sheath and ***helically encircles*** and is spaced apart from a stent, as recited in claims 23 and 29. Instead, the Fischell reference merely discloses an expandable flange 23 including a flower-like arrangement with multiple petals that are automatically expanded when the flange 23 is advanced from a guiding catheter 40.

Further, the Fischell reference does not teach or suggest an ostial locator comprising a distal region that assumes a ***spiral shape*** in the expanded configuration ***that is flattened out axially*** when the sheath is advanced into an ostium, as recited in claim 29. Accordingly, for these reasons, claims 23, 29, and their dependent claims are neither anticipated by nor otherwise obvious over the Fischell reference.

The Stewart reference fails to provide any additional teaching that may be properly combined with the Fischell reference to render the present claims obvious. First, the Stewart reference does not teach, or suggest anything about an ostial locator wire. Instead, the Stewart reference discloses a catheter assembly 190 for treatment of cardiac arrhythmia that includes a catheter body 192 including a distal portion 202 carrying electrodes 194 for ablating tissue. If such a catheter assembly were directed through the Fischell guiding catheter 40, the guiding catheter would be incapable of receiving a stent delivery device 12, as taught in the Fischell reference. Given the necessary size of the Stewart catheter assembly 190, it would prevent any other devices from being advanced through the Fischell guiding catheter. The Stewart catheter assembly 190 also could not accommodate receiving the Fischell stent delivery device since the Stewart catheter assembly does not include an internal lumen, but instead includes internal wires coupled to the electrodes 194 on the distal portion 202. Accordingly, if the Stewart catheter assembly replaced the Fischell flange 23, the Fischell guiding catheter 40 would be incapable of being used for its intended purpose. Accordingly, these references may not be properly combined, and, therefore, the present claims are not obvious over the Fischell and Stewart references.

Finally, the remaining cited references fail to disclose, teach, or suggest the features that are wholly absent from the Ischinger, Saltiel, and Fischell references. Accordingly, the present claims are obvious even if these references could somehow be properly combined with one another (which Applicant does not concede).

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Applicant hereby petitions for any extension of time necessary to make the present response timely. Applicant believes that a two month extension is currently required.

Respectfully submitted,
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Dated: May 19, 2009

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